

March 2023 Quarterly Activity Report

Melbourne, Australia; 28 April 2023: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has today released its Quarterly Activity Report for the three-month period ended 31 March 2023.

Key highlights:

- **New sites added for diabetic foot ulcer (DFU) trial and positive initial data released subsequent to the quarter**
- **Progressing start-up activities for a proposed phase 2 clinical trial in acute graft-versus-host disease (aGvHD), with IRB and ethics committee approval gained**
- **Planning continuing for new renal transplantation clinical trial, to be funded by Leiden University Medical Center (LUMC)**
- **Recruiting and treating patients in two ongoing clinical trials:**
 - **The phase 3 SCUIpTOR (structure-modifying treatment for medial tibiofemoral osteoarthritis) clinical trial and,**
 - **The DFU clinical trial**
- **Completed capital raise subsequent to the quarter with funds used to strengthen balance sheet and fund phase 2 clinical trial in aGvHD**
- **A\$13.5m in cash as at 31 March 2023**

Clinical update

DFU clinical trial underway

Cynata recently released encouraging initial data from the first 6 patients with chronic DFUs. Initial analysis has shown average ulcer size decreased at a greater rate in all three patients who received CYP-006TK, Cynata’s unique topical mesenchymal stem cell (MSC) product, versus patients who only received standard of care. These preliminary results in the first 6 patients provide the Company with initial data toward demonstrating safety and efficacy of CYP-006TK, in chronic wounds.

The DFU trial seeks to enrol 30 patients who are randomised to receive either: (i) CYP-006TK treatment for 4 weeks, followed by standard of care treatment; or (ii) standard of care treatment throughout the study.

During the quarter, Cynata announced the addition of 3 new clinical sites to the ongoing trial in DFU which will help the Company drive recruitment activity and achieve its goal in releasing headline data by the end of 2023. The newly added sites are based in Perth, Western Australia at the prestigious Royal Perth Hospital, Fiona Stanley Hospital, and Sir Charles Gairdner Hospital. Cynata also established its unique manufacturing process locally at the Royal Perth Hospital, to manufacture CYP-006TK product for the new sites. The new manufacturing site will complement Cynata’s local footprint in Adelaide where production and patient recruitment and treatment is ongoing. The Company looks forward to providing further updates as the trial progresses.

Activities for the planned Phase 2 trial in aGvHD progressing

Cynata recently received approval for its planned phase 2 aGvHD clinical trial from both an Institutional Research Board (IRB) service provider in the USA and the Australian Human Research Ethics Committee (HREC), both essential steps before a clinical trial can commence in the relevant jurisdiction. The Company is aiming to recruit

approximately 60 patients across multiple clinical centres in the US, Europe, and Australia, with the target number of around 30 clinical sites now very close to being met. The proposed trial is expected to commence in H1 2023 and Cynata remains confident that it will build on the success of its phase 1 trial in aGvHD which achieved all safety and efficacy endpoints.

Planning for new renal transplantation trial

Planning activities in collaboration with Leiden University Medical Centre (LUMC) continue for a proposed phase 1 clinical trial in renal transplantation with work ongoing towards securing customary regulatory, ethics and administrative approvals. The collaboration with LUMC, who is funding the trial, involves Cynata providing Cymerus™ MSCs and retaining full commercial rights. The proposed trial seeks to recruit 10 patients having undergone a renal transplant followed by administration of Cymerus MSCs and withdrawal of immunosuppressant (i.e. anti-rejection) medication. The primary endpoint of the renal transplantation trial will be observing the absence of graft loss 6 months post withdrawal. The trial is expected to commence mid-2023, subject to regulatory and ethics approvals. The global organ transplant immunosuppressant drugs market size is expected to reach US\$5.9 billion by 2026¹.

Progressing Phase 3 trial in osteoarthritis

The University of Sydney, in collaboration with Cynata, continues to progress patient treatment and recruitment in the Phase 3 SCUIpTOR trial focused on osteoarthritis patients. The trial aims to recruit 440 patients with osteoarthritis of the knee, making it the largest randomised controlled trial of MSCs conducted in patients with osteoarthritis worldwide, and is funded via an Australian Government National Health and Medical Research Council project grant. With over half the targeted number of subjects enrolled, the University of Sydney expects to complete patient recruitment at the end of this year with initial data readout to occur in late 2025. Importantly, Cynata retains full intellectual property and commercial rights of CYP-004, with the global osteoarthritis market expected to be US\$11.6bn².

Commercial update

Capital Raising

Subsequent to the quarter, Cynata raised A\$5m through a share Placement, led by specialist biotechnology fund and existing shareholder Bioscience Managers and supported by new and existing institutional investors. The capital raising demonstrates confidence in Cynata's proprietary technology to treat a wide range of diseases.

In order to provide an opportunity to all shareholders, a Share Purchase Plan ("SPP") was also announced and is currently open to eligible investors. The SPP closes at 5:00pm Monday 8 May 2023 (AEST). The funds raised from the capital raising will be used for the phase 2 clinical trial in aGvHD as well as working capital.

Further detail in relation to the Placement and SPP can be found from the ASX announcement released on 6 April 2023.

Corporate update

Financial position

Cynata closed the quarter with A\$13.5m in cash, as at 31 March.

¹ Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc., 2019

² Reflects OA market by 2025; Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025).



Net operating cash outflows for the quarter totalled A\$2.97m, compared to \$1.67m for the previous quarter with the main differences being a \$0.36m reduction in R&D expenditure for the March quarter offset by the receipt in the December quarter of an R&D Tax Incentive refund of \$1.65m. In item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately A\$185k comprised of salary paid to the Managing Director and fees paid to Non-Executive Directors.

Outlook

Cynata is moving towards its clinical milestones and is highly focused on recruiting and treating patients in its ongoing clinical trials. The Company continues to leverage the Cymerus platform technology to broader patient groups whilst striving for improved outcomes of care. With its cash position, Cynata will further develop its deep clinical product pipeline and fund the Company's regulatory approval process as it approaches commercialisation. We look forward to sharing more of our clinical results as we advance closer to our operational and growth targets for FY23 and beyond.

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata's lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. Planning for a Phase 2 clinical trial in GvHD under a cleared US FDA IND is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing. In addition, Cynata has demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

CYNATA THERAPEUTICS LIMITED

ABN

98 104 037 372

Quarter ended ("current quarter")

31 MARCH 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development *	(2,497)	(10,314)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(65)	(197)
(d) leased assets	-	-
(e) staff costs	(234)	(782)
(f) administration and corporate costs	(222)	(1,029)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	52	178
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives (2022 R&D Tax Incentive)	-	1,654
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,966)	(10,490)

* Includes US\$2 million Manufacturing Start-up Fee paid to FUJIFILM Corporation (Fujifilm) in July 2022 under a Strategic Partnership Agreement (as announced to ASX on 30 Sept 2021). Cynata may credit the Manufacturing Start-up Fee paid to Fujifilm against any amount which may become payable to Fujifilm under the Manufacturing Services Agreement (as announced to ASX on 29 Dec 2021).

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	-	-
2.6 Net cash from / (used in) investing activities	-	-

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Interest on Director's Loan received	-	-
3.10 Net cash from / (used in) financing activities	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	16,412	23,798
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,966)	(10,490)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	69	207
4.6	Cash and cash equivalents at end of period	13,515	13,515

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1 Bank balances	4,515	6,412
5.2 Call deposits	9,000	10,000
5.3 Bank overdrafts		-
5.4 Other (provide details)		-
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	13,515	16,412

6. Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1 Aggregate amount of payments to related parties and their associates included in item 1	185
6.2 Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>	

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
N/A		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,966)
8.2 Cash and cash equivalents at quarter end (item 4.6)	13,515
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	13,515
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.56
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 28 April 2023

Authorised by: The Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.